A Retrospective Review of the Technical Success of Endoscopic Stenting for Malignant Gastric Outlet Obstruction

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DECLARATION

I, Déan Tait, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

The completed manuscript has been submitted to TurnItIn.

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LIST OF TABLES AND FIGURES

ABBREVIATIONS

GOO	Gastric outlet obstruction
PUD	Peptic ulcer disease
SEMS	Self-expanding Metal Stent
ICU	Intensive care unit
NHLS	National Health Laboratory Service
CT	Computed tomography
LMIC	Lower and middle-income countries
CSEMS	Covered Self-expanding Metal stent
UCSEMS	Uncovered Self-expanding Metal Stent
ASGE	American Society for Gastrointestinal Endoscopy
GJ	Gastro-jejunostomy
EUS	Endoscopic ultrasound
EUS-GE	Endoscopic ultrasound guided gastro-enterostomy
LAMS	Lumen apposing metal stents

ABSTRACT

Introduction:

Palliation of patients with advanced and irresectable malignancies causing gastric outlet obstruction (GOO) with the endoscopic placement of a self-expanding metal stent (SEMS) has become standard. Internationally, technical success rates are high. This study reviewed endoscopic stent placement for malignant GOO compared to other international high-volume endoscopy units, looking into local success rates, pathology, and patient demographics.

Methods:

A retrospective review of patients presenting to the Groote Schuur Hospital Upper Gastrointestinal Unit with irresectable malignant GOO between 1 March 2018 and 31 August 2021 was performed, evaluating demographics, technical success, pathology, and immediate and late stent complications.

Results:

One hundred and fourteen patients, 44 (38.6%) female and 70 (61.4%) male, were referred for palliative stenting of malignant GOO; distal obstructive gastric cancer (74.6%) and obstructing pancreatic malignancies (14.9%) being the two most frequent indications. Median age was 63.5years (IQR: 53.25-70) with 48.2% having at least one comorbidity and 48.3% performance scores of 3 or 4. The majority (96; 85.7%) required only one stent, 15 patients (13.4%) had a second stent placed, and one patient required four stents. In total, 132 stent insertion attempts were undertaken. With primary placement, three technical failures were experienced. One stent was initially incorrectly placed but immediately correctly repositioned, while two failed insertions were referred for surgical gastrojejunostomy, equating to a technical success rate of 97.4%.Four immediate stent insertion related complications occurred (3.1%), two related to sedation, one stent placed too distally requiring repositioning and an oesophagogastric junction perforation with procedural death. Fifteen late-stent complications occurred with thirteen stent blockages due to tumour in-growth (10%), one stent fracture and one stent with poor radial expansion. The stent blockages occurred between 3 to 548 days after placement (median 107 days, IQR: 80 – 275 days). Salvage stenting was 100% successful in the 14 cases with late stent complications that required re-stenting.

Conclusion:

Technical insertion success rates of primary and salvage duodenal stenting for malignant GOO are on par with international high-volume units. The leading pathology locally is gastric adenocarcinoma, with palliative stenting remaining a feasible and accessible option.

PUBLICATION READY MANUSCRIPT

A RETROSPECTIVE REVIEW OF THE TECHNICAL SUCCESS OF ENDOSCOPIC STENTING FOR MALIGNANT GASTRIC OUTLET OBSTRUCTION

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Key words

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Introduction

Most gastric outlet obstruction (GOO) cases (50-80%) presenting to endoscopy units today are due to malignant obstruction.[1] While gastric and pancreatic malignancies are the most common causes of malignant GOO, lymphomas, duodenal, biliary tract, ampullary and metastatic malignancies may all cause GOO.[2] Although the overall incidence of gastric cancer appears to be declining in the western hemisphere, the proportion it now contributes to the aetiology of GOO has increased since benign peptic ulcer disease (PUD) as primary aetiology has markedly decreased.[3]

For patients with irresectable malignant disease and a short life expectancy, placement of a permanent self-expanding metal stent (SEMS) via endoscopy with fluoroscopic guidance is safe, effective, and now well established as the gold standard. The goal of stent placement is to relieve the obstructive symptoms and to improve early oral intake, thereby improving quality of life and avoiding the potential associated morbidity of surgery and anaesthesia.[4] Compared to surgical gastrojejunostomy, endoscopic stenting has an earlier return to oral intake and a shorter hospital stay.[5] While the cost of these stents can be considerable, the endoscopic placement of a gastroduodenal stent is comprehensively more cost effective when compared to surgery. This is mainly due to reduced post-procedural length of hospital stay and avoiding post-operative intensive care unit (ICU) admissions. In addition, patients with recurrent obstructions due to disease progression may benefit from salvage endoscopic stenting, with similar benefits.[6] Generally, technical success rates are high and refer to the successful endoscopic placement and deployment of the stent across the stricture or obstruction. A complicated or significantly altered anatomy with acute angulation or severe stenosis may contribute to technical failure of guidewire passage through the stricture or stent deployment across the obstruction. Technical success in duodenal strictures can be more complicated than distal gastric obstructions, owing to the curved configuration of the duodenum, as well as loop formation of the stent delivery system in a large, distended stomach.[7] In addition, due to late presentation, atonic, chronically distended and elongated stomachs filled with residual food have the added difficulties of poor visibility and challenges in reaching the area of obstruction.[8]

Early complications related to the endoscopic procedure include bleeding, abdominal pain, perforation, or incorrect positioning of the stent. As most stents are placed under conscious sedation, in the background of GOO aspiration remains a constant concern. Late complications

are invariably due to tumour overgrowth within the stent and rarely due to delayed stent migration.[4] There is currently insufficient evidence regarding the preferential placement of a partially covered, covered, or uncovered stent.[9,10] The benefits of partially or fully covered stents are potentially longer patency rates due to minimal tumour ingrowth. However, their migration rates are considerably higher than uncovered stents.[11] Secondary salvage stent placement for primary stent tumour ingrowth fortunately also has high technical and clinical success rates.[12,13]

The Groote Schuur Hospital Upper Gastrointestinal Unit is referred significant numbers of both benign and malignant GOO from a wide referral catchment area. This study reviewed stent placement for malignant GOO in our unit: the indications, immediate technical success, and the detection and subsequent management of early and late complications were investigated.

Methods

Study design & data source

A single center retrospective review of patients presenting to a tertiary hospital endoscopy unit with malignant gastric outlet obstruction requiring palliative stent placement was performed. The study was approved by the Human Research Ethics Committee of the University of Cape Town (HREC 218/2021). Data were extracted from an existing Upper Gastrointestinal Surgery Registry (HREC R031/2015).

Patients

All patients presenting to Groote Schuur Hospital with clinical features of GOO and requiring palliative endoscopic stenting of the upper gastrointestinal tract between 1 March 2018 and 31 August 2021 were evaluated for potential inclusion. GOO was defined as a mechanical obstruction with an inability to pass a standard gastroscope through the stricture, with clinical symptoms of GOO. Only patients with confirmed irresectable malignant strictures of the antrum, pylorus or duodenum were included in the study. Histological confirmation of malignancy was required before referral for stenting, with results accessed online via the National Health Laboratory Service (NHLS). Irresectability was determined by metastatic disease or local ingrowth visible on cross-sectional imaging by computerised tomography (CT). In addition, a performance status precluding any surgical intervention or oncological therapy with the patients only amenable to endoscopic stenting also allowed for inclusion.

Stents placed for benign indications or malignant proximal gastro-oesophageal obstructions were excluded.

Outcomes

The primary aim of this study was to determine the technical success of endoscopic stenting of irresectable malignant GOO and to determine if local success rates are comparable to international high-volume endoscopy units. Furthermore, this study aimed to determine if there are any differences between low and middle-income (LMIC) and developed countries as regards pathology of irresectable malignant GOO in those presenting for palliative endoscopic stenting.

Statistical analysis

Data exploration and analysis were done using Stata (Version 13.1; Stata Corp, College station, Texas, USA). Descriptive statistics were used to characterise patient demographics, histology, technical success and complication rates. Parametric data were reported as means with standard deviation and range, and non-parametric data were reported as median with inter-quartile range.

Results

Patients

During the study period of 40 months, a total of 660 upper gastrointestinal stents were placed for obstructive symptoms and evaluated for inclusion. Following exclusions due to endoscopic SEMS placements for proximal malignant upper gastrointestinal disease (489 oesophageal and oesophagogastric junction) and benign (39) indications, 132 stents were included for evaluation in this study.

For malignant irresectable GOO, 114 patients required endoscopic stenting of the distal antrum, pylorus, or duodenum. Patients presented at a median age of 63.5 years (IQR: 53.25 – 70) with the majority being male (n=70, 61.4%). Approximately half of the patients (48.2%) presented with one or more comorbidities, while the remaining 59 (51.8%) were not known with any documented comorbidities (Table 1). A significant amount (48,3%) of patients had performance scores of either PS3 or PS4 (Table 2). Fifty-three (46.5%) patients admitted to substance use known to cause chronic irritation of the gastric mucosa, of which the most significant proportion were smokers, equating to 44.7% of this study population (Table 3).

Technical success of stent deployment

Successful technical stent insertion was defined as correctly placing a stent endoscopically across the obstructing stricture at the first attempt, with no repositioning required and flow of contrast demonstrated through the stent into the distal lumen beyond the stricture. Within the cohort of 114 patients, a total of 132 endoscopic stent insertion attempts were undertaken. All stents placed for malignant GOO were uncovered. One hundred and eighteen stents were used during initial, primary placement. In four patients, a single stent was not deemed long enough to cover the length of the stricture adequately, necessitating a second overlapping stent placement during the primary procedure. Three technical failures were experienced during primary placement. One stent was initially incorrectly placed too distally, but then immediately correctly repositioned. In the other two patients, distal enteral access with a guidewire across the malignant stricture could not be achieved. The technical success of primary stent placement was therefore 97,4%.

Most patients (85.7%) required only one stent placement; however, fourteen salvage stents were placed, and all were deployed successfully to lie within the previously placed primary stents (Table 4).

Histopathology

Most stents (74.6%) were placed for GOO caused by gastric malignancy, of which only five cases were not caused by histologically confirmed adenocarcinoma (Table 3). These included lymphoma, adeno-squamous cell carcinoma, neuroendocrine tumour and two cases where the pathologists could not definitively report invasive malignancy, but “at least high-grade dysplasia”. Both patients had obvious malignant tumours on endoscopy with additional imaging findings confirming an irresectable, metastatic malignant process. After discussion by the multidisciplinary team, it was agreed that these were likely adenocarcinoma, and were then treated as such. Pancreatic adenocarcinoma was the next most common, followed by duodenal and periampullary malignancies. Seven other malignancies not arising from the stomach, pancreas or duodenum necessitated duodenal stenting. They were represented by metastatic or locally invasive malignancies from the liver, gallbladder, colon, endometrium, testicles, and retroperitoneum (Table 5).

Complications

Four (3.1%) immediate insertion-related complications included two patients with sedation-related bradypnoea resulting in oxygen desaturation but successfully treated with pharmacologic sedation-reversal agents with rapid improvement and no further complications. There was one incorrect stent placement (the stent was placed too far distally but was successfully repositioned during the same procedure) and one oesophageal perforation with procedural death. This death occurred in an elderly frail patient, who may not have been fit for the procedure, but stent insertion was performed at the discretion of the attending endoscopist. After completion of duodenal stenting and on scope retraction, a distal oesophageal perforation was found to have been incurred at some point during the procedure. Before this perforation could be attended to, the patient had a cardiac arrest with an unsuccessful resuscitation.

There were a further 15 late stent complications requiring repeat endoscopy. These included 13 incidents of stent occlusion by tumour (three in the same patient who had recurrent tumour ingrowth requiring a total of four stents). All recurrent obstructions from tumour ingrowth were successfully treated with an additional salvage stent placement within the primary stent. In those 13 incidences where tumour occlusion of the stent required reintervention by salvage stent placement, the time from stent placement to stent occlusion by tumour ranged from 3 days to 548 days with a median time of 107 days (IQR: 80 – 275 days). Early occlusions were seen with a suspected soft necrotic tumour where the uncovered stent caused a “cheese-wire” effect through the tumour, while later occlusion was seen from genuine tumour ingrowth.

There was one incident of the stent not opening sufficiently to allow for adequate gastric drainage, thus necessitating a second stent, and one incident of a late stent fracture with migration. This patient was completely asymptomatic, and the stent fracture with migration of a piece of stent was incidentally identified on CT. Despite this patient being initially asymptomatic at the time as regards recurrent GOO symptoms, she later returned with tumour ingrowth and GOO, requiring salvage stenting.

Discussion

The technical success rate of gastroduodenal stenting is high. In a pooled analysis of prospective literature, which included 1281 patients, Van Halsema *et al.* found it to be 97.3% (ranging between 89.1-100%), similar to our unit at 97.4%. Factors contributing to technical failure were largely found to be an inability to pass a guidewire across the malignant stricture,

insufficient deployment of the stent and migration of the stent during deployment.[14] While endoscopic stents placed due to pancreatic tumours with duodenal obstruction tend to be more technically challenging,[7] technical success is high, and the rate of re-intervention is low, given low rates of migration, good clinical success, and high patency rates, due to poor prognosis.[15] Given the local high burden of gastric malignancies, recurrent obstructions requiring re-intervention did occur. In the past, all stents in this unit were placed by using a side-viewing scope due to limitations with scope channel diameter. In this cohort, all stents were placed using a forward-viewing scope with a wide therapeutic channel. A front-viewing scope has the advantages of being more comfortable to use for the endoscopist and significantly shorter procedure times. While there is no difference in the technical and clinical success rates, side-viewing scopes may have a higher risk of perforation and bleeding.[16]

While several primary malignancies can cause GOO, advanced, irresectable gastric and pancreatic malignancies are the most prevalent. Studies internationally from high income countries have found pancreatic malignancies to be the most frequent pathology, followed by gastric cancer.[4,10,17] However, in this study, gastric adenocarcinoma dominated as the leading cause by nearly 75%. In the 2020 Global Cancer Statistics, Africa has the lowest incidence of gastric cancer worldwide. Similarly, the prevalence of pancreatic cancer is lower than in high-income countries.[18] Despite gastric cancer only accounting for 1.6% (male 2.1% and female 1.1%)[19] of all reported malignancies in South Africa, regrettably most will be surgically irresectable at primary presentation. Several African studies have confirmed this low overall incidence of gastric cancer; commonly, patients tend to present late with advanced disease and poor performance status.[20] The reported combination of low socio-economic status with significant diagnostic delay and resultant detrimental effects on nutrition and subsequently performance status, are suspected to be similar contributing factors locally. The predominance of distal gastric adenocarcinoma with the antral / pyloric location of the tumour is a known risk factor for rapid occlusion and subsequent mortality.[20]

Though in this unit we use uncovered stents in malignant GOO, there are currently many different SEMS available, that can broadly be divided into covered (CSEMS) and uncovered (UCSEMS) stents. In the American Society for Gastrointestinal Endoscopy (ASGE) Guideline of 2021, the panel found insufficient evidence in the literature to recommend one stent over the other.[21] A large, randomized controlled trial by Yamao *et al*. of 366 patients compared the use

of a CSEMS vs USEMS and found no difference between immediate technical success, clinical success, adverse events, and overall patient survival.[9] There was a significant difference regarding late stent complications, with a much higher rate of stent migration in the CSEMS group, but more tumour in-growth in the UCSEMS group. Since it is technically easier to place a salvage stent through a previous stent with tumour ingrowth than it would be to reposition or retrieve a migrated stent, we prefer in our setting to exclusively use uncovered stents for malignant GOO. When these late stent complications do occur and the stent must be retrieved or another salvage stent needs to be placed, technical success rates are high. Locally our salvage stent placement has a 100% technical success rate, which falls within the 92%-100% range reported in the literature.[22,23]

Cost is always an essential factor in resource-constrained countries such as South Africa, as is the availability of hospital and ICU beds. Several studies calculating cost-effectiveness concluded that the cost of palliation with endoscopic stents was much less than with surgical gastro-jejunostomy (GJ) and allowed patients to go home sooner.[6,24] However, there are advantages to surgical GJ, including lower re-obstruction rates and, therefore, less re-interventions, with comparable clinical and technical success. An increased survival rate has been noted with GOO secondary to gastric cancer, but not pancreatic cancer, likely due to the poor prognosis of pancreatic cancer presenting with GOO.[5] Surgical GJ should be considered in patients with a better performance score and life expectancy, even if it means a longer hospital stay and cost.[25] Many of our patients referred for stenting have advanced disease with a poor performance score, so the advantages of avoiding an anaesthetic, the morbidity of surgery, ICU admission, plus a quick return to oral intake and early discharge home are clear. Like most low to middle-income countries, the study site functions in a resource-constrained environment, with distinct financial benefits to early discharge post endoscopic stenting.

In 2012 Binmoeller and Shah described a novel endoscopic ultrasound (EUS) technique to create a gastro-jejunal anastomosis.[26] Since then, various methods have been developed to perform an EUS-guided gastroenterostomy (EUS-GE) using lumen apposing metal stents (LAMS).[4] While the procedure is more technical to perform, more time consuming and requires skilled endoscopists, it has the advantage of avoiding open surgery with the associated morbidity and mortality risks. Compared to the more traditional placement of a SEMS, EUS-GE has shown lower rates of stent failure due to tumour ingrowth, stent migration or other

obstruction, thus longer patency rates and less need for re-intervention.[27] This is likely due to the stenting occurring away from the primary tumour site. In a systematic review and meta-analysis by Iqbal *et al*. of 285 patients, EUS-GE had a pooled technical success of 92% (88%-95%; 95%CI) and clinical success of 90% (85%-94%).[28] Adverse events can include stent mis-deployment, bleeding, pneumo- or haemoperitoneum, leakage, abdominal pain and peritonitis (0%-26%).[29] Although the expertise and LAMS are available locally, this option is reserved for isolated situations where standard endoscopic placement of SEMS has failed and the patient is not fit for surgery.

Limitations

Most patients referred to the study site are often from outlying regions and district hospitals. The clear limitations of our study are that we are unable to comment on the degree of subsequent improvement of GOO symptoms or duration of clinical success, or on the length of survival post palliative stenting. We remain dependent on the primary clinicians to refer patients back to us for re-intervention, should they suspect any late stent-related complications amenable to correction.

Conclusion

Technical success rates of both primary and salvage endoscopic stent placement for malignant distal gastric and duodenal obstructions in this study site are high and compares well to international figures. We have a high burden of gastric carcinoma, with many patients having advanced irresectable disease or poor performance scores. Until screening and earlier detection rates improve locally, palliation of gastric cancer remains the most frequent approach for this pathology. Local palliative endoscopic stenting of distal gastric and duodenal obstructions remains a very useful and cost-effective non-surgical option for the relief of GOO symptoms in a LMIC setting with resource constraints and limitations.

RECORDED CHARACTERISTICS	ALL PARTICIPANTS
Demographics	
Median age (IQR) in years	63.5 (53.25-70)
	n (PERCENTAGE)
Male gender	70 (61.4 %)
Co-morbidities	
Arthritis	3 (2.6 %)
Cardiovascular disease	3 (2.6 %)
CVA/ Vascular dementia	3 (2.6 %)
Diabetes	14 (12.3 %)
HIV	7 (6.1 %)
Hypertension	34 (29.8 %)
Hypercholesterolaemia	3 (2.6 %)
Obstructive lung disease	7 (6.1 %)
Other	8 (7.0 %)
None	59 (51.8 %)

Table 1. Patient demographics and clinical characteristics in 114 patients undergoing endoscopic stenting for irresectable gastric outlet obstruction.
CVA: cerebral vascular accident; HIV: human immunodeficiency virus.

PERFORMANCE SCORES	ALL PARTICIPANTS n (PERCENTAGE)
PS0	11 (9.6%)
PS1	16 (14%)
PS2	26 (22.8%)
PS3	41 (36%)
PS4	14 (12.3%)
Not reported	6 (5.3%)

Table 2. Performance scores reported in 114 patients undergoing endoscopic stenting for malignant gastric outlet obstruction

SUBSTANCE USE	ALL PARTICIPANTS n (PERCENTAGE)
Ethanol	7 (6.1 %)
Non-steroidal anti-inflammatories	4 (3.5 %)
Smoker/recent ex-smoker	51 (44.7 %)
No substances	52 (45.6 %)
Not reported	9 (7.9 %)

Table 3. Substance use reported in 114 patients undergoing endoscopic stenting for irresectable gastric outlet obstruction.

NUMBER OF STENTS PER PATIENT	n (PERCENTAGE)
1 Stent	96 (85.7%)
2 Stents	15 (13.4%)
4 Stents	1 (0.9%)
TOTAL = 130	112

Table 4. Total number of stents inserted per patient in patients presenting with irresectable gastric outlet obstruction.

PATHOLOGY	n (PERCENTAGE)
Gastric Malignancy	85 (74.6%)
Adenocarcinoma	80 (70.2 %)
"At least high-grade dysplasia"	2 (1.8 %)
Adeno-squamous carcinoma	1 (0.9 %)
Lymphoma	1 (0.9 %)
Neuroendocrine tumour	1 (0.9 %)
Pancreatic malignancy	17 (14.9%)
Duodenal malignancy	3 (2.6%)
Lymphoma	2 (1.8 %)
Neuroendocrine tumour	1 (0.9 %)
Periampullary malignancy	2 (1.8%)
Other	7 (6.1%)
Liver malignancy (HCC, Lymphoma)	2 (1.8 %)
Gallbladder malignancy	1 (0.9 %)
Testicular seminoma (metastatic)	1 (0.9 %)
Retroperitoneal teratoma	1 (0.9 %)
Colonic adenocarcinoma (metastatic)	1 (0.9 %)
Endometrial adenocarcinoma (metastatic)	1 (0.9 %)

Table 5. Underlying pathology in 114 patients undergoing endoscopic stenting for irresectable gastric outlet obstruction.
HCC: hepatocellular carcinoma.

COMPLICATION	n (PERCENTAGE)
STENT INSERTION-RELATED COMPLICATIONS	**4 (3.1%)**
Sedation-related	2 (1.5%)
Incorrect stent position	1 (0.8%)
Oesophageal perforation and procedural death	1 (0.8%)
LATER STENT-RELATED COMPLICATIONS	**15 (11.5%)**
Stent occlusion by tumour	13 (10.0%)
Stent fracture	1 (0.8%)
Failure of stent opening adequately	1 (0.8%)

Table 6. Complications related to stenting of irresectable gastric outlet obstruction.

REFERENCES

1. Tringali A, Giannetti A, Adler DG. Endoscopic management of gastric outlet obstruction disease. *Annals of gastroenterology*. 2019;32(4):330-337. doi:10.20524/aog.2019.0390
2. Jeong SJ, Lee J. Management of gastric outlet obstruction: Focusing on endoscopic approach. *World journal of gastrointestinal pharmacology and therapeutics*. 2020;11(2):8-16. doi:10.4292/wjgpt.v11.i2.8
3. Samad A, Khanzada TW, Shoukat I. Gastric outlet obstruction: change in etiology. *Pak J Surg*. 2007;23(1):29-32.
4. Troncone E, Fugazza A, Cappello A, et al. Malignant gastric outlet obstruction: Which is the best therapeutic option? *World journal of gastroenterology : WJG*. 2020;26(16):1847-1860. doi:10.3748/wjg.v26.i16.1847
5. Hong J, Chen Y, Li J, et al. Comparison of gastrojejunostomy to endoscopic stenting for gastric outlet obstruction: An updated Systematic Review and Meta-analysis. *The American journal of surgery*. 2021;doi:10.1016/j.amjsurg.2021.10.038
6. Fisher AV, Hanlon B, Fernandes-Taylor S, et al. Natural history and cost analysis of surgical bypass versus endoscopic stenting for the palliative management of malignant gastric outlet obstruction. *HPB (Oxford, England)*. 2020;22(4):529-536. doi:10.1016/j.hpb.2019.08.009
7. Ye B-W, Lee K-C, Hou M-C. Endoscopic management of malignant gastric outlet obstruction. *Journal of the Chinese Medical Association*. 2021;84(4):346-353. doi:10.1097/JCMA.0000000000000502
8. Lopera JE, Brazzini A, Gonzalez A, Castaneda-Zuniga WR. Gastroduodenal stent placement: Current status. *Radiographics*. 2004;24(6):1561-1573. doi:10.1148/rg.246045033
9. Oh DMD, Lee SSMDP, Song TJMDP, et al. Efficacy and safety of a partially covered duodenal stent for malignant gastroduodenal obstruction: a pilot study. *Gastrointestinal endoscopy*. 2015;82(1):32-36.e1. doi:10.1016/j.gie.2014.11.039
10. Yamao K, Kitano M, Chiba Y, et al. Endoscopic placement of covered versus uncovered self-expandable metal stents for palliation of malignant gastric outlet obstruction. *Gut*. 2020;
11. Tringali A, Costa D, Anderloni A, Carrara S, Repici A, Adler DG. Covered versus uncovered metal stents for malignant gastric outlet obstruction: a systematic review and meta-analysis. *Gastrointestinal endoscopy*. 2020;92(6):1153-1163.e9. doi:10.1016/j.gie.2020.06.033
12. Jin EH, Kim SG, Seo JY, Im JP, Kim JS, Jung HC. Clinical outcomes of re-stenting in patients with stent malfunction in malignant gastric outlet obstruction. *Surgical endoscopy*. 2016;30(4):1372-1379. doi:10.1007/s00464-015-4338-z
13. Endo S, Takiguchi S, Miyazaki Y, et al. Efficacy of endoscopic gastroduodenal stenting for gastric outlet obstruction due to unresectable advanced gastric cancer: A prospective multicenter study. *Journal of surgical oncology*. 2014;109(3):208-212. doi:10.1002/jso.23486
14. van Halsema EE, Rauws EAJ, Fockens P, van Hooft JE. Self-expandable metal stents for malignant gastric outlet obstruction: A pooled analysis of prospective literature. *World journal of gastroenterology : WJG*. 2015;21(43):12468-12481. doi:10.3748/wjg.v21.i43.12468
15. Orr J, Lockwood R, Gamboa A, Slaughter JC, Obstein KL, Yachimski P. Enteral Stents for Malignant Gastric Outlet Obstruction: Low Reintervention Rates for Obstruction due to Pancreatic Adenocarcinoma Versus Other Etiologies. *Journal of gastrointestinal surgery*. 2020;25(3):720-727. doi:10.1007/s11605-019-04512-6
16. Kumar V, Ghoshal UC, Mohindra S, Saraswat VA. Palliation of malignant gastroduodenal obstruction with self-expandable metal stent using side- and forward-viewing endoscope: Feasibility and outcome. *JGH open*. 2019;3(1):65-70. doi:10.1002/jgh3.12110

17. Tringali A, Didden P, Repici A, et al. Endoscopic treatment of malignant gastric and duodenal strictures: a prospective, multicenter study. *Gastrointestinal Endoscopy*. 2014;79(1):66-75. doi: 10.1016/j.gie.2013.06.032
18. Sung H, Ferlay J, Siegel RL, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA: a cancer journal for clinicians*. 2021;71(3):209-249. doi:10.3322/caac.21660
19. Herbst MC. Fact Sheet on Stomach Cancer. Online document. Cancer Association of South Africa. Updated May 2021. https://cansa.org.za/files/2021/05/Fact-Sheet-on-Stomach-Cancer-NCR-2017-web-2021.pdf
20. Bang GA, Savom EP, Oumarou BN, et al. Clinical epidemiology and mortality risk factors of gastric cancer in a sub-Saharan African setting: a retrospective analysis of 120 cases in Yaoundé (Cameroon). *The Pan African medical journal*. 2020;37:104-104. doi:10.11604/pamj.2020.37.104.25422
21. Jue TL, Storm AC, Naveed M, et al. ASGE guideline on the role of endoscopy in the management of benign and malignant gastroduodenal obstruction. *Gastrointestinal endoscopy*. 2021;93(2):309-322.e4. doi:10.1016/j.gie.2020.07.063
22. Kim CG, Choi IJ, Lee JY, et al. Outcomes of second self-expandable metallic stent insertion for malignant gastric outlet obstruction. *Surgical endoscopy*. 2013;28(1):281-288. doi:10.1007/s00464-013-3185-z
23. Mo JW, Kim YM, Kim J-H, Shin SY, Youn YH, Park H. Clinical outcomes after multiple self-expandable metallic stent placement using stent-in-stent technique for malignant gastric outlet obstruction. *Medicine (Baltimore)*. 2020;99(21):e19432-e19432. doi:10.1097/MD.0000000000019432
24. Johnsson E, Thune A, Liedman B. Palliation of Malignant Gastroduodenal Obstruction with Open Surgical Bypass or Endoscopic Stenting: Clinical Outcome and Health Economic Evaluation. *World journal of surgery*. 2004;28(8):812-817. doi:10.1007/s00268-004-7329-0
25. Jang S, Stevens T, Lopez R, Bhatt A, Vargo JJ. Superiority of Gastrojejunostomy Over Endoscopic Stenting for Palliation of Malignant Gastric Outlet Obstruction. *Clinical gastroenterology and hepatology*. 2019;17(7):1295-1302.e1. doi:10.1016/j.cgh.2018.10.042
26. Binmoeller KF, Shah JN. Endoscopic ultrasound-guided gastroenterostomy using novel tools designed for transluminal therapy: a porcine study. *Endoscopy*. 2012;44(5):499-503. doi:10.1055/s-0032-1309382
27. Ge PS, Young JY, Dong W, Thompson CC. EUS-guided gastroenterostomy versus enteral stent placement for palliation of malignant gastric outlet obstruction. *Surgical endoscopy*. 2019;33(10):3404-3411. doi:10.1007/s00464-018-06636-3
28. Iqbal U, Khara H, Hu Y, et al. EUS-guided gastroenterostomy for the management of gastric outlet obstruction: A systematic review and meta-analysis. *Endoscopic ultrasound*. 2020;9(1):16-23.
29. Stefanovic S, Draganov PV, Yang D. Endoscopic ultrasound guided gastrojejunostomy for gastric outlet obstruction. *World journal of gastrointestinal surgery*. 2021;13(7):620-632. doi:10.4240/wjgs.v13.i7.620

UNIVERSITY OF CAPE TOWN
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12 July 2021

HREC REF: 434/2021

Dr G Chinnery
Surgery Gastroenterology/ Upper GIT
FHS
Email: galyachinnery@gmail.com
Student: drdeantait@gmail.com

Dear Dr Chinnery

PROJECT TITLE: A RETROSPECTIVE REVIEW OF THE TECHNICAL SUCCESS OF ENDOSCOPIC STENTING FOR MALIGNANT GASTRIC OUTLET OBSTRUCTION-MMED CANDIDATE-DR DEAN TAIT-SUB-STUDY LINKED TO 031/2015

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.

Approval is granted for one year until the 30 July 2022.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Dr Dean Tait will also be involved in this study.

Please quote the HREC REF 434/2021 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Western Cape Government

GROOTE SCHUUR HOSPITAL

Enquiries: Dr Bernadette Eick
e-mail: GSHResearch.Request@westerncape.gov.za

DR GALYA CHINNERY
SURGERY GASTROENTEROLOGY

E-mail: galyachinnery@gamil.com

Dear Dr Chinnery

RESEARCH PROJECT: A Retrospective Review of the Technical Success of Endoscopic Stenting for Malignant Gastric Outlet Obstruction. MMed Candidate: Dr Dean Tait

Your recent letter to the hospital refers.

You are granted permission to proceed with your research, which is valid until **30 July 2022.**

Please note the following:

a) Your research may not interfere with normal patient care.
b) Hospital staff may not be asked to assist with the research.
c) **Confidentiality must always be maintained.**
d) No additional costs to the hospital should be incurred as indicated in your Annexure 2 i.e. Lab, consumables or stationery. **If access to TRACK Care/NHLS is required, kindly attach our letter of approval to the application form and approach Information Management to assist with data.**
e) **No patient folders may be removed from the premises or be inaccessible.**
f) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
g) **Should you at any time require photographs of your subjects, please obtain the necessary indemnity forms from our Public Relations Office (E45 OMB or ext. 2187/2188).**
h) Should you require additional research time beyond the stipulated expiry date, please apply for an extension.
i) Please discuss the study with the HOD before commencing.
j) Please introduce yourself to the person in charge of an area before commencing.
k) On completion of your research, please forward any recommendations/findings that can be beneficial to use to take further action that may inform redevelopment of future policy / review guidelines.
l) Please contact Michelle Riley (Patient Fees) at ext. 2276 to ascertain if there will be charges for conducting the Research and to obtain a quote or to discuss charges
m) **Kindly submit a copy of the publication or report to this office on completion of the research.**
n) **At no time should any posters encouraging patients to partake in research, be displayed within a clinical area.**
o) **Please adhere to ALL COVID-19 regulations and Groote Schuur Hospital policies.**

I would like to wish you every success with the project.

Yours sincerely

DR BERNADETTE EICK
CHIEF OPERATIONAL OFFICER
Date: 26 January 2022

C.C. Mr. L. Naidoo, Dr. B. Jacobs, Prof. L. Cairncross, Mr. A. Mohamed

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MANUSCRIPT PREPARATION

Refer to articles in recent issues for the presentation of headings and subheadings. If in doubt, refer to 'uniform requirements' - **www.icmje.org**. Manuscripts must be provided in **UK English**.

The manuscript should contain the title, abstract, keywords, article text and references.

The title page should be submitted as a supplementary file and should include:

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Abbreviations

All abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.

Scientific measurements

Scientific measurements must be expressed in SI units except blood pressure (mmHg) and haemoglobin (g/dl). Litres is denoted with a lowercase 'l' e.g. 'ml' for millilitres). Units should be preceded by a space (except for %), e.g. '40 kg' and '20 cm' but '50%'. Greater/smaller than signs (> and 40 years of age) should also be preceded by a space e.g. > 20 years. No spaces should precede ± and °, i.e. '35±6' and '19°C'.

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The manuscript must be in Microsoft Word or RTF document format. Text must be 1,5-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes, except for Tables). *The manuscript must be free of track changes.*

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If tables or illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.

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REFERENCES

Authors must verify references from the original sources. *Only complete, correctly formatted reference lists will be accepted.* Reference lists may be generated with the use of reference manager software, but the final document must be delinked from the reference database or otherwise generated manually. Citations should be inserted in the text as superscript, e.g. These regulations are endorsed by the World Health Organization,[2] and others.[3,4-6] The superscript reference number should come after the punctuation mark.

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Journal references: Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. Stat Med 1998;289(1):350-355. [http://dx.doi.org/10.1000/hgjr.182] [PMID: 2764753]

Book references: Jeffcoate N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975:96-101. *Chapter/section in a book:* Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA jun, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974:457-472.

Internet references: World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: World Health Organization, 2002. http://www.who.int/whr/2002 (accessed 16 January 2010).

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